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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,224	BRAKSTAD ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8 and 12-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/7/2006, 6/16/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

Status of Application

1. The response filed January 29, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claim 1 has been amended.

   b. Claim 2 and 11 has been cancelled.

2. Claims 1, 3-8 and 12-14 are pending in the case.

3. Claims 1, 3-8 and 12-14 are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

6. New grounds of rejection are set forth in the current office action.

Information Disclosure Statement

7. The information disclosure statement (IDS) submitted on 8/7/2006, 6/16/2008 has been considered by the examiner in regards to Bianco et al. and Wolter 1993, which have translations submitted by Applicant on January 29, 2009. Hofmann (DE 2559569) and (DE25559570) are not considered as the translations provided are incomplete. There are only fragments of the claims and examples presented in the translation and several areas are blank. Pages are missing and only certain paragraphs presented and translated but without context as to if it is the Abstract or particular paragraphs of the specification. They have not been considered.

New Grounds of Rejection

8. Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is directed to the amount of dry supplement/kg dry feed which is confusing as the term may be applicable to animal feed, it does not provide a standard for human delivery as most standard human delivery is not through feed but pharmaceutical dosage forms, food, or drink. It does not allow one of skill in the art to ascertain the metes and bounds of the invention. For purposes of prosecution, the claim is viewed to be administration to animal that is not a human.

11. Regarding claim 5, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations of the desiccant following the phrase are part of the claimed invention. It does not allow one of skill in the art to ascertain the metes and bounds of the invention.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1, 3-5, 8, 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (U.S.Pat. Pub. No. 2002/0150653) in view of The Food and Nutrition Board (Dietary Reference Intakes (DRIs); Estimated Average Requirements for Groups).

Bailey et al. teaches the concept of a food, feed, and vitamin preparations comprising folates and multivitamins for human of animal consumption. The compositions were preferably stored with antioxidants and reducing agents to extend shelf life. The pH of the final composition can be optimized based on the desired stability properties, preferably with acidity less than about pH 4. The compositions exemplified comprised citric acid, ascorbic acid, vitamin E, pyridoxine (vitamin B6), folic acid (vitamin B9), vitamin B12 (cyanocobalamin), ferrous fumarate, and silica (desiccant).

Several examples are taught Bailey et al. with different forms including cereal, tablets, drinks, cat food, bird feed, and infant formula with varying amounts of vitamins and minerals within the RDI and far beyond the RDI (see Example 6). Bailey teaches that vitamin and nutrient components can be present in amounts that vary considerably from NRC recommendations and can be greater than 25%, greater than 50% and even greater than or equal to 100% of the daily requirement for the nutrient. Several examples have ascorbic acid or citric acid and have the ratios for the acid with B6, B9, and B12 (i.e. Example 3/tablet-B9:ascrobic=0.545mg/0.06g=9.08mg/g, B12:ascorbic=6ug/0.06g=100ug/g).Bailey also teaches the method of administering the compositions to humans and animals, including horses, for the treatment of conditions

including intestinal malabsorption, increasing the dietary intake of folate which improves performance as it would improve immune response and reduce risks to cancer, peripheral vascular disease, and nervous system disorders as Bailey teaches that a deficiency in folate would result in a susceptibility to these conditions (see full document, specifically Abstract, Paragraph 3-7, 11, 15-21, 30-36, 38-49).

Bailey et al. does not expressly teach an example with the specifics of where to total amount of the B6, B9, and B12 together is 10-50mg/g of the supplement, at the specific range of 0.5-30mg/g of the acid, 0.1-10mg/g of the acid, and 1-1500ug/g of the acid, wherein the acid is formic, citric, lactic, propionic, ascorbic, fumaric, acetic, or benzoic. Bailey also does not teach the administration of the supplement based on weight in humans.

Bailey does teach the combination of all these elements (such as ascorbic acid) together as supplements in food, feed, and vitamin preparations. Bailey also provides examples of these forms citing that the amounts of these components can be varied based on the nutritional requirements.

The Food and Nutrition Board (Dietary Reference Intakes (DRIs); Estimated Average Requirements for Groups) teaches that there are general estimated average requirements for vitamin intake for different groups, ages, and gender. There is also different recommended requirement for infants, children, and adults.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to optimize the amounts of the vitamins in the supplement

based on and beyond the amounts in the DRI table, and modify the supplement as needed for the form and patient population, as suggested by Bailey and the Food and Nutrition Board, and produce the instant invention. It would have been obvious to one of skill in the art to modify the form of the supplement dependent the target population, mode of administration, and vitamin levels of the components as Bailey teaches several forms with a range of vitamin levels and combinations and teaches that these levels vary considerably depending on the desired amounts/levels. The amounts desired can be present in the recommended levels (e.g. RDI or NRC) but can also vary considerably from these recommendations depending on the manufacturers' desire.

Bailey expressly states that manufacture often exceed the dosage recommended by the NRC (e.g. folate), and the amounts for the daily requirement can be greater than 25% and even greater than 100%. As shown by the examples, the components such as vitamin levels and delivery forms can be modified depending the mode of delivery and the vitamin content desired. The Food and Nutrient Board teaches general recommended intakes and also teaches that they vary depending on the targeted population. The amounts vary when it is an infant, child, or an adult which also goes to body weight as you cannot give the same of amount of a vitamin that is safe for an adult to an infant as the level may be toxic to an infant due their body size/weight. Active agents are routinely calibrated based on body weight for children and is the standard in medicine. In the absence of evidence or a showing of the criticality of the specific ratios in the claims, a general optimal range whereby the ratios and percent ranges are clustered in a nexus that can be arrived through optimization when the general

conditions are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

One of ordinary skill in the art would have been motivated to do this because it is desirable to optimize the amounts of the vitamins and nutritional components in a supplement form desired, to attain the desired biological results for the patient population targeted.

14. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (U.S.Pat. Pub. No. 2002/0150653) in view of the Food and Nutrition Board (Dietary Reference Intakes (DRIs);Estimated Average Requirements for Groups) as applied to claims 1, 3-5, 8, 12-14 above, and in view of Lawrence (Nutrient Requirements and Balancing Rations for Horses).

The teachings of Bailey et al. in view of the Food and Nutrition Board are addressed above.

Bailey et al. in view of Food and Nutrition Board does not expressly teach an example with the administration of the supplement based on weight in horses or animals.

Lawrence teaches that nutrient requirements will vary based on the weight of the horse and that requirements increase in direct proportion to body weight (Introduction, Maintenance-paragraphs 1-2).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust the amount of supplement, as suggested

Lawrence, and produce the instant invention. It would have been obvious to one of skill in the art to adjust the amount of supplement depending on the size of the horse/animal as demonstrated by Lawrence, it is known in the art that the daily requirements for horses vary according to size, activity, and type as addressed by Lawrence and is known to one in the art to modify the amounts based on weight.

One of ordinary skill in the art would have been motivated to do this because it is desirable to customize and optimize the amounts of the vitamins and nutritional components in a supplement based on the weight of the patient as it is desirable in the art to balance and meet the nutritional requirements to attain the desired biological results such as having the animal maintain its body weight and condition/degree of fitness (Lawrence-Introduction).

Response to Arguments

15. Applicant's arguments with respect to claims have been considered but are moot in view of the new grounds of rejection. Applicant's submission the declaration is persuasive and the standing 112 rejections are withdrawn. The translations submitted are appreciated and have been reviewed as addressed above.

Conclusion

16. Claims 1, 3-8 and 12-14 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612